

Translation

PATENT COOPERATION TREATY

PCT/JP2004/006038



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference E0006TW02W	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2004/006038	International filing date (day/month/year) 23 April 2004 (23.04.2004)	Priority date (day/month/year) 23 April 2003 (23.04.2003)
International Patent Classification (IPC) or national classification and IPC A61K 31/122, A61P 35/00, 35/04, 43/00		
Applicant EISAI CO., LTD.		

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of _____ (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
- This report contains indications relating to the following items:
 - ☒ Box No. I Basis of the report
 - ☐ Box No. II Priority
 - ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☐ Box No. IV Lack of unity of invention
 - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☒ Box No. VI Certain documents cited
 - ☐ Box No. VII Certain defects in the international application
 - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 22 September 2004 (22.09.2004)	Date of completion of this report 01 March 2005 (01.03.2005)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 9

because:

- ☒ the said international application, or the said claims Nos. 9
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claim 9 relates to a method for treatment of the human body by therapy, which does not require an international preliminary examination by the International Preliminary Examining Authority in accordance with PCT Article 34(4)(a)(i) and PCT Rule 67.1(iv).

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 9

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the
Administrative Instructions in that:

- | | | |
|----------------------------|--------------------------|-----------------------------------|
| the written form | <input type="checkbox"/> | has not been furnished |
| | <input type="checkbox"/> | does not comply with the standard |
| the computer readable form | <input type="checkbox"/> | has not been furnished |
| | <input type="checkbox"/> | does not comply with the standard |

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with
the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

- ☐ see Supplemental Box for further details.

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	1-8, 10	NO
Inventive step (IS)	Claims		YES
	Claims	1-8, 10	NO
Industrial applicability (IA)	Claims	1-8, 10	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

- Document 1: (M. Otsuka, et al.), Hepatology, Meeting Info.: 53rd Annual Meeting on the Liver, 2002, Vol. 36, No. 4, Part 2, page 445A
- Document 2: (Toshihiko Mizuta, et al.), Abstracts from the 38th Meeting of the Liver Cancer Study Group of Japan, 2002, page 135
- Document 3: (Toshihiko Mizuta, et al.), Journal of the Japanese Society of Gastroenterology, 2002, Vol. 99, special supplement (general meeting), page A192
- Document 4: (Yukihiro Koike, et al.), Liver, 2002, Vol. 43, suppl. (1), page A64
- Document 5: (K. Miyazawa, et al.), Blood, Meeting Info.: 43rd Annual Meeting of the American Society of Hematology, Part 1, 2001, Vol. 98, No. 11, Part 1, page 353a
- Document 6: (F. Y. H. Wu, et al.), Life Sciences, 1993, Vol. 52, No. 22, pages 1797-1804
- Document 7: (H. Okayasu, et al.), Anticancer Research, 2001, Vol. 21, pages 2387-2392
- Document 8: (Y. Nishikawa, et al.), J. Biol. Chem., 1995, Vol. 270, No. 47, pages 28304-28310
- Document 9: An Anticancer Effect of Vitamin K, (Tatsuyuki Miyakawa, et al.), 2000, Vol. 74, No. 2, pages 74-76
- Document 10: JP, 6-305955, A (Eisai Co., Ltd.), 1 November, 1994 (01.11.94)

Claims 1-8 and 10

The subject matters of claims 1-8 and 10 do not appear to be novel or to involve an inventive step in view of documents 1-10 cited in the ISR.

Documents 1-10 describe that menatetrenone inhibits metastasis, invasion, repullulation, growth, etc., of cancer, and the subject matters of claims 4 and 8 of the present application are not different from the inventions described in documents 1-10 in terms of the matters for the specifying of inventions.

The applicant claims in the written reply submitted on 22 May 2005 that documents 1-10 do not describe or suggest any relationship of menatetrenone with the expression of MMP, etc. The invented agents, however, of the present application are in essence merely for the inhibition of metastasis, invasion, repullulation, growth, etc., of cancer, and so the invention of the present application cannot be distinguished from those described in documents 1-10 as agents.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
JP 2004-107330 A [E, X]	08.04.2004	22.08.2003	26.08.2002
JP 2004-67513 A [E, X]	04.03.2004	12.07.2002	12.06.2002
WO 2004/56351 A1 [E, X]	08.07.2004	19.12.2003	20.12.2002

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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